UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CELLTRION HEALTHCARE CO., LTD. and CELLTRION, INC.,

Plaintiffs,

-against-

KENNEDY TRUST FOR RHEUMATOLOGY RESEARCH,

Defendant.

14 Civ. 2256 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

Plaintiffs Celltrion Healthcare Co, Ltd. and Celltrion Inc. (collectively, "Celltrion" or "Plaintiffs") bring this action against Defendant Kennedy Trust for Rheumatology Research ("Kennedy") for a declaratory judgment that three patents held by Kennedy are invalid because of improper tactics used by Kennedy to obtain the patents. Celltrion seeks this declaration to enable its biosimilar drug Remsima to enter the United States market. Defendants move to dismiss the complaint for lack of subject matter jurisdiction, pursuant to Federal Rule of Civil Procedure 12(b)(1); or for a stay pending the outcome of reexamination/reissue proceedings by the U.S. Patent and Trademark Office ("PTO"). For the reasons that follow, Defendant's motion to dismiss is granted.

BACKGROUND

A. The Parties

i. Kennedy

Kennedy, "the pioneer in the discovery of methods of treating patients with rheumatoid arthritis ("RA") and other auto-immune diseases," owns the three patents at issue in this

litigation: U.S. Patent Nos. 7,846,442 (the "'442 patent"), 8,298,537 (the "'537 patent"), and 8,383,120 (the "'120 patent"). Defendant Kennedy Trust's Memorandum in Support of its Motion to Dismiss Plaintiff Celltrion's Complaint for Lack of Subject Matter Jurisdiction Pursuant to Fed. R. Civ. P. 12(b)(1) ("Def. Mem."), at 5, 6. These patents cover methods of treating rheumatoid arthritis "by administering a combination of an anti-TNFα antibody (such as Remicade ®) and the known rheumatoid arthritis drug methotrexate." Complaint for Declaratory Judgment ("Compl."), at ¶ 4. In 1998, Janssen Biotech, Inc. ("Janssen"), a licensee of Kennedy, received FDA approval for its drug infliximab, which contains the monoclonal antibody cA2, under the trademark Remicade. Def. Mem. at 7-8. Originally, the FDA approved Remicade to treat Crohn's disease; in later years, Remicade was approved for the treatment of RA, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. *Id.* at 8.

ii. Celltrion

Celltrion, a biopharmaceutical company that specializes in developing biosimilars,[1] has spent several years, and large sums of money, developing Remsima, a biosimilar version of Remicade. Compl. ¶¶ 19-22. Celltrion began developing Remsima in 2008 and has invested more than $112 million in the process. *Id.* ¶ 19. In 2010, Celltrion applied for and received approval from multiple countries to begin clinical trials for Remsima. *Id.* ¶ 25. Remsima has since been approved in 47 nations, and approval is pending in 23 other countries. *Id.* ¶ 29. Celltrion began the process of obtaining FDA approval to market Remsima in the U.S. on July 10, 2013, when Celltrion met with FDA representatives to receive guidance on additional studies

[1] A biosimilar is a biologic product which is highly similar to an already licensed "reference product." Plaintiffs' Memorandum of Law in Opposition to Defendant Kennedy Trust's Motion to Dismiss the Complaint or Stay the Action ("Pl. Mem."), at 3; 42 U.S.C. § 262(i)(2). Because of the complexity of the molecules that comprise biologic drugs, it is impossible to demonstrate that a follow-on biologic is identical to an approved biologic. Def. Mem. at 4. The FDA has not yet approved a biosimilar of an antibody drug. Compl. ¶ 5.

needed. *Id.* ¶ 31. At that meeting, the FDA recommended a short follow-up clinical trial. *Id.* ¶ 32. Celltrion successfully completed this trial, a bridging study comparing Remsima with Remicade sourced from the E.U. and the U.S., in March 2014. *Id.* Meanwhile, Celltrion submitted an Investigational New Drug ("IND") application pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act on October 2, 2013, and the FDA accepted it on November 18, 2013. *Id.* ¶ 31. Celltrion has scheduled a final meeting with the FDA, during which Celltrion plans to finalize the specifics of its application, and Celltrion anticipates that the FDA will approve Remsima for RA treatment in the first quarter of 2015. *Id.* ¶ 33.[2] The patents at issue are currently under reexamination and reissue proceedings before the PTO. Compl. ¶¶ 41, 42, 44.

B. The Biologics Price Competition and Innovation Act

Congress passed the Biologics Price Competition and Innovation Act (the "BPCIA") in 2009. *See* 42 U.S.C. § 262. The BPCIA provides a statutory framework under which biologics manufacturers may apply for, and obtain, a license by showing its product is a biosimilar to another product, known as the "reference product." *Id.* § 262(i)(2), (k). This provides a quicker and less expensive pathway for biosimilar manufacturers to obtain FDA approval for products with "no clinically meaningful differences" from the reference product. *Id.* § 262(i)(2)(B). The reference product receives exclusivity for a period of twelve years. *Id.* § 262(k)(7)(A).

The BPCIA contains a dispute resolution mechanism in order to ensure that patent disputes are resolved prior to the end of the reference product's exclusivity period. Pl. Mem. at 3. Through this process, the BPCIA ripens otherwise unripe patent disputes and provides a

[2] Because the existence of subject matter jurisdiction is assessed by considering circumstances present at the time of the filing of the complaint, the Court disregards the parties' discussion of factual developments that have occurred since Celltrion filed its complaint on March 31, 2014.

pathway for the resolution of these disputes before the exclusivity period terminates, enabling biosimilar products to enter the market promptly upon the expiration of exclusivity. *Id.* Pursuant to this process, the applicant provides a copy of its application to the reference product sponsor within twenty days after the application is accepted for review. 42 U.S.C. § 262(l)(2). Within sixty days of receipt of this application, the reference product sponsor is to respond, identifying patents for which an infringement claim "could reasonably be asserted." *Id.* § 262(l)(3)(A)(i). The parties then negotiate these claims in good faith and if, after fifteen days of negotiations, the parties have not reached an agreement, the reference product sponsor may then bring an action for patent infringement. *Id.* § 262(l)(6)(B). The applicant must also provide to the reference product sponsor a notice of commercial marketing no later than 180 days before marketing of the biosimilar is to commence, at which time the reference product sponsor may seek a preliminary injunction against the applicant. *Id.* § 262(l)(8)(A). Neither party may bring a declaratory judgment action while the process is under way; if the applicant fails to comply with these procedures, the reference product sponsor may bring a declaratory judgment action, but the applicant may not. *Id.* § 262(9)(A), (B). The BPCIA addresses the role of patent owners in the provision discussing recipients of confidential information; the Act provides that "[a] representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the . . . applicant of . . . [its] agreement to be subject to the confidentiality provisions" of the Act. *Id.* § 262(l)(1)(B)(iii).

DISCUSSION

A. Applicable Law

Article III of the Constitution and the Declaratory Judgment Act impose the additional jurisdictional requirement of an actual controversy. *See Nike, Inc. v. Already, LLC*, 663 F.3d 89, 95 (2d Cir. 2011). The Act provides that "[i]n a case of actual controversy," a federal court "may declare the rights . . . of any interested party seeking such declaration." 28 U.S.C. § 2201(a). The Second Circuit applies a totality-of-the-circumstances test to determine the existence of a justiciable controversy in intellectual property cases. *See Nike*, 663 F.3d at 95 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007)). Under this test, the court considers whether "the adversity of legal interests that exists between the parties is real and substantial and admits of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be on a hypothetical state of facts." *Id.* at 95-96 (citing *MedImmune*, 549 U.S. at 127) (internal quotation marks and alterations omitted); *Telebrands Corp. v. Exceptional Prods.*, 2011 WL 6029402, at *2 (D.N.J. Dec. 5, 2011) ("[T]he Court must decide 'whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" (quoting *MedImmune*, 549 U.S. at 127)). District courts "possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1376 (Fed. Cir. 2012) (citing *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1996)).

B. Analysis

1. Actual Case or Controversy

Kennedy argues that Celltrion has failed to establish the existence of an actual case or controversy because it has not yet engaged in meaningful preparation to conduct potentially infringing activity and it has not adequately demonstrated injury or the threat of injury. Def. Mem. at 9-16. Celltrion counters that the dispute is ripe because Celltrion has substantially prepared to bring Remsima to the U.S. market, and because Kennedy has previously litigated against the Remsima antibody and has expressed an intent to pursue infringement claims against Celltrion over Remsima. Pl. Mem. at 8-17. In support of this argument, Celltrion points to the amount of money it has invested in Remsima; the completion of its clinical trials; its close work with the FDA; its manufacturing facilities; and its ability to have stockpiles of Remsima prepared upon receiving FDA approval. Pl. Mem. at 8-12.

While these steps exhibit a true intention to bring Remsima to the U.S. market, Celltrion is simply too far from receiving FDA approval of Remsima for the exercise of declaratory judgment jurisdiction to be proper. Kennedy outlines the numerous steps that would have to occur for there to even be the potential for patent infringement here: Celltrion's application would have to be accepted for review; Celltrion would have to become the first ever biosimilar approved by the FDA; Celltrion's application would have to include cA2; Celltrion would have to receive approval of Remsima for the same use as Remicade; and these events would have to occur prior to the August 1, 2016 expiration date of the patent involved. Def. Mem. at 11-14. Although these steps are not wholly speculative or unlikely, they demonstrate that any opinion of the Court on the present claims would be largely based on the disfavored "hypothetical state of facts." The parties spend a great deal of time arguing about the likely time frame of FDA

approval, but neither side is able to show that its asserted time frame is more than speculation. While the Court notes that Celltrion has invested substantial sums of money and has diligently pursued U.S. approval, these approval preparations are simply not at a stage that can support a declaratory judgment action.

Even were the aforementioned events to occur, Kennedy has not expressed a clear intent to pursue infringement claims against Celltrion. *See Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1340 (Fed. Cir. 2008) ("The defendants' lack of any 'concrete claim of a specific right' is an important factor weighing against a finding of an actual controversy, particularly given that there has been no actual injury."). Celltrion argues that Kennedy has engaged in prior litigation sufficient to show that it is likely that Kennedy will pursue litigation against Celltrion over its patent rights. Pl. Mem. at 14-18. In support of this argument, Celltrion points to Kennedy's counterclaims filed in foreign jurisdictions against Remsima; its infringement suits against other companies over the parent patents of those at issue here; and the fact that Kennedy maintains a legal fund of £16.3 million, of which it spent £6.12 million on intellectual property protection in 2012. Compl. ¶¶ 45-52; Pl. Mem. at 17-18. Yet Kennedy argues that it has granted licenses to Celltrion in Europe, Australia, and Hong Kong and has indicated a willingness to grant Celltrion a license in the U.S. and Canada. *See* Def. Mem. at 14. This difference of opinion further demonstrates that the issue between the parties has not yet ripened into a controversy. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007) (declaratory judgment is appropriate in situations where "the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right prior to the suit.").

The parties here have not yet taken adverse positions. While "[p]rior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy," *Prasco*, 537 F.3d at 1341, Celltrion has failed to show that the likelihood of suit from Kennedy is presently so great as to demonstrate the existence of a live case or controversy. Likewise, public statements regarding the patents owned by a patent owner, and that it defends the patent it owns, "do not suffice to show an 'imminent threat'" of litigation. *Sandoz Inc. v. Amgen Inc.*, 2013 WL 600069, at *2-3 (N.D. Cal. 2013).

Celltrion has not demonstrated that Kennedy has taken "a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do." *SanDisk Corp.*, 480 F.3d at 1381. Considering the totality of the circumstances present here, there is no justiciable controversy that gives rise to declaratory judgment jurisdiction.

2. The BPCIA Framework

Even if the Court were to find that Celltrion had engaged in sufficient meaningful preparation to market Remsima and that the threat of injury was sufficiently demonstrable, the Court would still exercise its discretion to decline to hear this case in light of the existence of the BPCIA statutory framework for the resolution of patent disputes in the licensing of biosimilars. In enacting the BPCIA, Congress provided a dispute resolution mechanism specifically for disputes arising out of the manufacture and marketing of biosimilars. The BPCIA seeks to promptly and efficiently resolve patent disputes in order to ensure that approved biosimilars may be sold in the U.S. as soon as they are ready for market. There is no reason to believe, and Celltrion has failed to demonstrate or even allege, that the dispute resolution procedure established by the BPCIA would be insufficient to resolve any patent disputes here.

The only court to have addressed the propriety of a declaratory judgment action involving a biosimilar prior to engagement with the BPCIA dispute resolution process held that failure to comply with the information exchange requirements of the BPCIA barred the applicant from bringing a declaratory judgment action against the reference product sponsor. *See Sandoz*, 2013 WL 6000069, at *2. Similarly, Celltrion's attempts to skirt the BPCIA's dispute resolution mechanisms while reaping the benefits of its approval process is improper. Indeed, the inherent tension in Celltrion's position demonstrates why the Court should decline to exercise jurisdiction here: Celltrion urges the Court that the case is ripe for review, yet argues that the BPCIA does not apply because the time has not yet arisen for the parties to engage in the necessary information-exchange process. Pl. Mem. at 18-19. This position is untenable.

Celltrion argues that it would be an abuse of discretion for the Court to decline to exercise jurisdiction because the BPCIA simply delays disputes and does not resolve them. In addition, Celltrion argues that the instant dispute is not appropriate for the BPCIA pathway because Kennedy is not the reference product sponsor, but the patent owner. Pl. Mem. at 18-22. While it is true that the BPCIA envisions the dispute resolution process to involve the applicant and the reference product sponsor, the BPCIA does provide for a level of involvement by the patent owner, *see* 42 U.S.C. § 262(l)(3)(A), (l)(1)(B)(iii). Moreover, the procedures of the BPCIA are designed to enable the narrowing of patent disputes and the crystallization of infringement claims. As Kennedy asserts, Celltrion's argument simply demonstrates that its dispute against Kennedy is truly unripe: before Celltrion can market Remsima, it must resolve any disputes regarding the patents involved with Janssen, the reference product sponsor. Def. Reply at 6. Once the time for participation in the BPCIA dispute resolution process occurs, and once any disputes between Celltrion and Janssen arise and are clarified, then a ripe case or

controversy may exist between Celltrion and Kennedy. Prior to that time, subject matter jurisdiction is lacking. As for Celltrion's delay argument, a federal court does not have jurisdiction over a declaratory judgment action simply because the dispute may arise in the future and the relevant statutory framework does not resolve it in a time frame to the plaintiff's liking.

The BPCIA purposefully keys its dispute resolution procedures to the occurrence of certain events on the path to FDA approval. Celltrion has failed to show why this carefully crafted and well-timed procedure should be avoided here. Should Celltrion have a ripened patent dispute against Kennedy once it properly engages in the BPCIA dispute resolution procedures and once it is further along the pathway towards approval of its biosimilar, Celltrion may litigate those issues at that time.

CONCLUSION

For the foregoing reasons, Kennedy's motion to dismiss is granted. Kennedy's motion for a stay is mooted by this Court's decision. The Clerk of Court is directed to terminate the pending motion and to close this case.

Dated: New York, New York
December 1, 2014

SO ORDERED

PAUL A. CROTTY
United States District Judge